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EXAMINER	
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ART UNIT	PAPER NUMBER
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Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☐ THE PERIOD FOR RESPONSE:

a) ☐ is extended to run _____ or continues to run _____ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☒ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 12-9-97 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☒ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☒ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: The proposed clms add the new issue of a probe complexity of about 40 KB as well as the new issue of interfase target material. These issues would require further consideration and/or search.

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ ~~Upon the filing of an appeal,~~ the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

   Claims allowed: none
   Claims objected to: none
   Claims rejected: 1

   However;

   ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The ~~affidavit, exhibit or request for reconsideration~~ has been considered but does not overcome the rejection because REMARKS Have of record that are still applicable due to the above noted non-entry of the amdts. See also the attached further response.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

08/477,316

PTOL-303 (REV. 5-89)

Further Explanation of Item 4 on the attached Advisory Action:

Applicants arguments based on claim amending are moot in overcoming the rejections due to the above discussed non-entry of the amendment, filed 12/9/97.

Other arguments are responded to as follows:
The proposed amendment to the word "probes" in proposed amended claim 1, line 3, combined with the explanation in the REMARKS, filed 12/9/97, on page 5 therein would have overcome the rejection based on singular "probe" versus "probes" citation unclarity in the claim. The other 2nd paragraph rejection based on a lack specificity or hybridization condition limitations in the claim would not, however, been overcome because in hybridization probe assays both what is stained or detected versus what is "not" are critical aspects of such assays. The omission of any mention of specificity/hybridization conditions in the claim therefore leaves open a critical target discriminatory feature of the invention. It is noted that staining of nucleic acid has been performed in the art to stain most if not all of a chromosome and thus a method of staining may simply require the staining of some minimal chromosomal material as a requirement without necessarily "not" staining some other portion thereof. Thus, the art that may or may not be applicable to be considered in methods as instantly claimed critically must be evaluated regarding what the metes and bounds of the stained material is. Without specifying it clearly in the claims no

amount of discussion in the specification negates this well known breadth to hybridization assay, especially chromosomal staining type methods.

Applicant argue the applicability of Weissman et al. by arguing that chromosomal rearrangement assays are not suggested or motivated therein. Applicants are referred to the office action, mailed 9/4/96, wherein Weissman et al. at column 2, line 13, through column 4, line 5, is pointed to. Specifically, in column 2, lines 16-20, the translocation of marker genes from one chromosomal region to another is described. This is clearly gene rearrangement in contrast to the arguments of applicants. The last argument directed to interphase target material is moot in that this is a new issue and one of the reasons for the non-entry of the amendment, filed 12/9/97. It is acknowledged that Weissman et al. does not contain disclosure of interphase chromosomal target material.

The double-patenting rejections are maintained as not being argued.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the

submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unseccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

January 6, 1998

Ardin H. Marschel

ARDIN H. MARSCHEL
PRIMARY EXAMINER
GROUP 1800